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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,956	07/11/2000	ROBERT ANDREW BADLEY	IMIN.P-019	6821
21121	7590	11/03/2003	EXAMINER	
OPPEDAHL AND LARSON LLP P O BOX 5068 DILLON, CO 80435-5068			GABEL, GAILENE	
			ART UNIT	PAPER NUMBER
			1641	22
DATE MAILED: 11/03/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/554,956

Applicant(s)

BADLEY ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-16 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-16 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Amendment Entry***

1. Applicant's response filed 7/18/03 in Paper No. 21 is acknowledged and has been entered. Currently, claims 1-3, 5-16, and 22 are pending and are under examination.

**Rejections Withdrawn**

***Claim Rejections - 35 USC § 112***

2. In light of Applicant's argument the rejection of claims 1-3, 5-16, and 22 under 35 U.S.C. 112, second paragraph, is hereby, withdrawn.
3. The rejection of claims 1-3, 7-10, and 13-16 under 35 U.S.C. 102(b) as being anticipated by Schramm et al. (WO 91/05262) is being withdrawn, in favor of a new ground of rejection under 35 U.S.C. 102(b) as being anticipated by Schramm et al. (US Patent Number 5,281,539).
4. In light of Applicant's argument the rejection of claims 1-3, 7-8, 11, and 14-16 under 35 U.S.C. 102(b) as being anticipated by Partin et al. (US Patent 5,082,630), is hereby, withdrawn.
5. In light of Applicant's argument, the rejections of claims 5, 6, 12 and 22 under 35 U.S.C. 103(a) as being unpatentable over Schramm et al. or Partin et al. (US Patent 5,082,630) in view of Badley et al. (US Patent 6,294,391), Presta et al. (US Patent 6,025,166), and Alcock et al. (US Patent 5,736,188), are hereby, withdrawn.

**New Grounds of Rejection**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 7-10, and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Schramm (US Patent 5,281,539).

Schramm et al. disclose a method of detecting the presence of an analyte in a sample comprising providing a first surface having a displaceable moiety reversibly immobilized, exposing the first surface to a sample wherein any analyte in the sample displaces the displaceable moiety, and detecting a signal. Schramm et al. teach contacting the first surface, upon which a displaceable moiety such as an antibody or analyte has been reversibly bound, with a sample wherein analyte in the sample displaces the reversibly bound moiety causing the displaced moiety to bind to a second surface upon which a specific antibody is bound and detecting the signal which can be produced by fluorescence or enzyme labels. Schramm et al. also teach that the two surfaces can be on separate or same supports and that planar, porous, or particulate surfaces may be used (see Abstract, especially column 5, line 51 to column 6, line 2, and column 4, line 42 to column 5, line 4). Schramm et al. disclose using electrodes to detect the detectable signal, i.e. sensors, wherein the analyte, if present, continually

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displaces the displaceable moiety and then is continually captured by the capture antibody so that the measured signal from the sensors continuously changes, with the concentration of the analyte captured on the sensor (see column 8, lines 27-62 and Figure 7).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 11 is rejected under 35 U.S.C. 102(b) as being unpatentable over Schramm (US Patent 5,281,539) in view of Partin et al. (US Patent 5,082,630).

Schramm et al. has been discussed supra. Schramm et al. differs from the instant invention in failing to teach that the detectable signal comprises the generation of or the modulation of, an evanescent or acoustic wave.

Partin et al. disclose a fiber optic detector for use in immune testing. In practice, Partin et al. disclose coating a distal end of an optical fiber or waveguide (first surface) with antibody, then saturating the fiber with fluorescent-tagged drug derivative, i.e. antigen (displaceable moiety). Thereafter, the fiber is exposed to an airborne sample of the analyte, i.e. drug, to be detected. If the analyte is present, the analyte molecules displace some of the bound, fluorescent-tagged derivative, resulting in a decrease (modulation) in signal as detected by a detecting diode. The extent of the decrease is proportional to the concentration of drug molecules in the surrounding environment. See column 4, lines 49-64 and column 4).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to capture and detect the signal generated in the method of Schramm using the waveguide as taught by Partin because Schramm appears to be generic in the type of detection method used, depending on the labels used, and Partin taught that the optical fiber for use in detection has the advantage of being sensitive even at extremely low concentrations of analyte.

8. Claim 5, 6, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm (US Patent 5,281,539) in view of Presta et al. (US Patent 6,025,166).

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Schramm et al. has been discussed supra. Schramm et al. differs from the instant invention in failing to disclose specifically using fusion protein in claim 5 as a displaceable moiety.

Presta et al. disclose using fusion proteins (chimeric proteins) in competitive displacement assays. Specifically, Presta et al. tested binding specificity of fusion proteins in a cellular environment, wherein the competitive displacement assay was done with iodinated neurotrophins.

Schramm et al. and Presta differ from the instant invention in failing to disclose specifically using a mimitope in claim 6 as a displaceable moiety or in claim 22 as an intervening moiety.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the intervening moiety or the displaceable moiety in the method of Schramm et al., with fusion or chimeric proteins as taught by Presta because Presta specifically taught application of fusion proteins in displacement assays such as in the methods of Schramm et al.. It would also have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute mimitopes as intervening or displaceable moieties in the method of Schramm and Presta, because mimitopes and fusion proteins constitute obvious variations of binding members or analogs for use in recognizing specific epitopes in the immunological assay art.

### ***Response to Arguments***

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9. Applicant's arguments with respect to claims 1-3, 5-16, and 22 have been considered but are moot in view of the new grounds of rejection.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Gailene R. Gabel  
Patent Examiner  
Art Unit 1641  
October 30, 2003

*g*

*Christopher L. Chin*

CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP ~~1800~~/1641